



**UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/008,957	01/20/98	MORIARTY	R

BULLWINKEL PARTNERS  
SUITE 1300  
19 SOUTH LASALLE STREET  
CHICAGO IL 60603-1493

HM12/0410

EXAMINER
BADIO, B

ART UNIT	PAPER NUMBER
1616	19

DATE MAILED: 04/10/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/008,957

Applicant(s)  
Moriarty et al.

Examiner  
Barbara Badio

Group Art Unit  
1616



☐ Responsive to communication(s) filed on \_\_\_\_\_

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-19 is/are pending in the application.

Of the above, claim(s) 7-9 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-6 and 10-19 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### **First Office Action on the Merits of a Continued Prosecution Application**

#### ***Continued Prosecution Application***

1. The request filed on February 10, 2000 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/008,957 is acceptable and a CPA has been established. An action on the CPA follows.

#### **Status of the Application**

2. The amendment filed December 13, 1999 was entered. Claims 1-19 are pending in the present application. Claims 7-9 stand withdrawn from consideration, as being drawn to a non-elected invention. Claims 1-6 and 10-19 stand rejected as indicated below.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Objections***

4. The objection of claims 2-4, 10-12 and 15-17 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn.

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***Claim Rejections - 35 USC § 112***

5. The rejection of claims 5-6 and 18-19 under 35 USC 112, second paragraph is withdrawn.

***Claim Rejections - 35 USC § 103***

6. The rejections of claims 1-6 and 10-19 under 35 USC 103(a) over (1) Holick et al. ('538); (2) Holick et al. ('643); (3) Bishop et al. ('429) and claims 1-4, 10-12 and 15-17 under 35 USC 103(a) over Gulbrandsen et al. ('790) is maintained.

Applicant agrees that the cited references disclose a generic group of vitamin D derivatives which includes applicants'  $1\alpha$ -hydroxyvitamin D<sub>5</sub> compounds. However, applicant argues that the claimed compound (i.e.,  $1\alpha(\text{OH})\text{D}_5$ ) shows unexpectedly improved properties or properties not present in the prior art based on the declaration of Dr. Robert Moriarty. The argument was considered but not persuasive for the following reasons.

Applicant refers to several prior art references in support that vitamin D compounds are known to increase serum calcium levels. However, as indicated in the previous Office Action, there is evidence in the prior art that the instantly claimed compounds have a lower tendency or inability to cause hypercalcemia and/or hypercalciuria (see US Patent 5,763,429, col. 5, line 60 - col. 6, line 13) and, thus, are useful in the treatment of certain cancers. In response, applicant argues that Bishop

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('429) does not teach or suggest that the claimed compound has substantially lower calcemic activity than the others. The examiner agrees that the prior art does not single out the claimed compound nor does it suggest that said compound has lower calcemic activity than the other compounds. However, the ordinary artisan would not expect all of the compounds of the genus taught by the prior art to have the same degree of activity. He would expect a range of activity of the compounds taught by the prior art and, thus, that some of the compound would have a lower hypercalcemic and/or hypercalciuric activity as shown by the declaration of Dr. Moriarty. Thus, the results shown by the declaration is not considered unexpected or unobvious.

Even if the examiner agreed that the declaration of Dr. Moriarty shows unexpected and unobvious results, it does not commensurate in scope with the instant claims. In other words, applicant has only shown a difference between  $1\alpha(\text{OH})\text{D}_4$  and  $1\alpha(\text{OH})\text{D}_5$ . Vitamin  $\text{D}_3$  derivatives are not considered the closest prior art compounds and neither would a comparison between  $1\alpha(\text{OH})\text{D}_5$  and vitamin  $\text{D}_3$  derivatives be considered a true comparison. The examiner notes that a comparison between  $1\alpha(\text{OH})\text{D}_5$  and  $1\alpha,25(\text{OH})_2\text{D}_4$  would also not be considered a true comparison.

Applicant also states that there is a long felt but unmet need for a vitamin D compound useful in the treatment of cancer without the harmful increase in serum calcium levels. It is noted that the compounds taught by Bishop ('429) are said to be useful in the treatment of cancer and to also have a lower tendency or inability to cause

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hypercalcemia and/or hypercalciuria and, thus, overcome the shortcomings of the known active vitamin D<sub>3</sub> compounds. Bishop teaches that vitamin D<sub>4</sub> and vitamin D<sub>2</sub> are less toxic than vitamin D<sub>3</sub> (see the entire articles, especially col. 6, line 57 - col. 7, line 18).

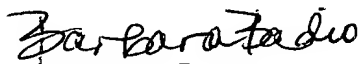
For these reasons and those given in Paper Nos. 3 and 11, the rejections of claims 1-6 and 10-19 under 35 USC 103(a) over (1) Holick et al. ('538); (2) Holick et al. ('643); (3) Bishop et al. ('429) and claims 1-4, 10-12 and 15-17 under 35 USC 103(a) over Gulbrandsen et al. ('790) is maintained.

***Telephone Inquiry Contacts***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara Badio whose telephone number is (703) 308-4595. The examiner can normally be reached between 7:30 am and 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, José Dees, can be reached on (703) 308-4628. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

  
Barbara Badio  
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April 7, 2000